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Veracyte Announces that New Data from Multiple Studies Demonstrate “Real World” Performance of Afirma GSC and Xpression Atlas in Thyroid Cancer Diagnosis

Study findings reported at the American Thyroid Association Annual Meeting

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Oct. 6, 2018-- Veracyte, Inc. (Nasdaq: VCYT) announced today that new findings from six studies reinforcing the “real world” performance of the next-generation Afirma Genomic Sequencing Classifier (GSC) and the Afirma Xpression Atlas in thyroid cancer diagnosis were presented at the 88th Annual Meeting of the American Thyroid Association (ATA). The meeting is being held October 3-7 in Washington, D.C.

Researchers from leading institutions presented posters showing that use of the Afirma GSC at their respective centers significantly increased the identification of benign thyroid nodules among those deemed indeterminate – not clearly benign or malignant – following cytopathology review, compared to the original Afirma test.

- The Ohio State University – Researchers compared results of 113 indeterminate samples that were tested with the Afirma GSC to those of 403 samples using the earlier version of the test (the Afirma Gene Expression Classifier, or GEC). The Afirma GSC identified 74.1 percent of the nodules as benign, compared to 48.4 percent with the GEC, an increase of 53 percent. The overall surgery rate among all patients who underwent genomic testing decreased by more than half – from 42.2 percent with the GEC to 20.2 percent with the GSC.
- Cleveland Clinic – Comparing results of 46 samples tested with the Afirma GSC between July 2017 and December 2017 with 182 samples tested with the original test between December 2011 and July 2017, researchers found that the GSC identified 67.4 percent as benign, compared to 41.8 percent with the GEC – an increase of 61 percent. The overall surgery rate for nodules tested with the GSC was 32.6 percent, compared to 47.3 percent with the original test, a decrease of 31 percent.
- Brigham and Women’s Hospital – Researchers evaluated results for 583 thyroid nodules tested with either the Afirma GSC (n=97) or GEC (n=486) between 2011 and 2018. They found that the Afirma GSC identified 64.9 percent of nodules as benign, compared to 47.9 percent with the GEC, an increase of 35 percent.

“Our results show that with the improved testing, we sent significantly fewer patients to surgery,” said Dr. Christian Nasr, medical director of the Thyroid Center in the Endocrinology & Metabolism Institute at Cleveland Clinic in Cleveland, Ohio. “Additionally, when patients went to surgery following ‘suspicious’ results, we were more likely to find cancer. Our findings suggest that the next-generation test can help more patients avoid unnecessary thyroid surgery, while focusing healthcare resources on the patients who are more likely to need them.”

Additionally, in two oral presentations, researchers shared the first “real world” Afirma Xpression Atlas data, providing insights into the distribution of a wide range of gene variants and fusions across key categories of indeterminate thyroid nodules and Afirma GSC results. For example, among 13,549 indeterminate thyroid nodules evaluated using the Afirma GSC and Xpression Atlas, more than a quarter (25.9 percent) of GSC-suspicious nodules (in primary risk categories known as Bethesda III/IV) contained RAS variants. Additionally, RET, NTRK, BRAF and ALK fusions were only found in GSC-suspicious, versus GSC-benign, cases (in all Bethesda categories).

“Having detailed genomic information about thyroid nodules that are malignant or suspicious for cancer may in some cases help inform surgical decision-making for these patients,” said Dr. Allan C. Golding of Memorial Healthcare System in Hollywood, Fla. “Additionally, the wide range of gene alterations detected by the Xpression Atlas may provide further insights into pathway activation and potential cancer treatment targets for patients with thyroid cancer.”

The field of precision medicine is progressing rapidly, and multiple targeted therapies are in clinical trials or have been approved for treatment of advanced cancers that harbor specific genomic alterations. In the new data presented at the ATA conference, genomic changes (or alterations) targeted by these new therapies were identified in Afirma GSC-suspicious cases by the Xpression Atlas.

“The new data shared at the ATA annual meeting add to the growing library of real-world evidence demonstrating the Afirma GSC’s performance across multiple institutions in reducing unnecessary surgeries in thyroid cancer diagnosis,” said Bonnie Anderson, Veracyte’s chairman and chief executive officer. “Additionally, these new study data for the Afirma Xpression Atlas demonstrate the ability of our robust RNA sequencing platform to provide rich genomic content that may help inform surgery decisions and treatment options for patients with suspected or confirmed thyroid cancer. The extensive gene alteration data that it provides becomes increasingly important in the era of targeted therapies.”

For more information, please visit the Veracyte Booth #201 or www.afirma.com/ATA2018.

About Afirma

Veracyte’s Afirma solution provides a comprehensive offering in thyroid cancer diagnosis for physicians evaluating patients with thyroid nodules. The Afirma Genomic Sequencing Classifier combines RNA sequencing data with machine learning to identify patients with benign thyroid nodules among those with indeterminate cytopathology results in order to avoid unnecessary surgery and preserve the thyroid. Since the commercial introduction of Afirma in 2011, Veracyte has performed over 100,000 genomic tests, and estimates it has saved more than 40,000 patients from unnecessary thyroid

surgery and removed an estimated $800 million in surgery costs from the healthcare system. The Afirma classifier is proven in over 20 published clinical studies, is included in most leading clinical guidelines and is covered as medically necessary by Medicare and all major U.S. health plans. The company's Afirma Xpression Atlas platform, introduced in May 2018, provides extensive genomic data that may inform surgery strategy and treatment options for patients with thyroid nodules that are suspicious for cancer or cancerous. The RNA sequencing-based platform measures 761 DNA variants and 130 RNA fusions in over 500 genes shown to be associated with thyroid cancer on thyroid nodule fine needle aspiration samples.

About Veracyte

Veracyte (Nasdaq: VCYT) is a leading genomic diagnostics company that improves patient care by providing trustworthy and actionable answers to challenging clinical questions. The company's products uniquely combine advanced genomic technology, clinical science and machine learning to provide answers that give physicians and patients a clear path forward, informing both diagnosis and treatment decisions without the need for costly, risky surgeries that are often unnecessary. Since its founding in 2008, Veracyte has commercialized three genomic tests, which are transforming the diagnosis of thyroid cancer, lung cancer and idiopathic pulmonary fibrosis and collectively target a $2 billion market opportunity. Veracyte is based in South San Francisco, California. For more information, please visit www.veracyte.com and follow the company on Twitter (@veracyte).

Cautionary Note Regarding Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "expect," "believe," "should," "may," "will" and similar references to future periods. Examples of forward-looking statements include, among others, our belief that our genomic tests will transform the diagnosis of thyroid cancer, lung cancer and idiopathic pulmonary fibrosis; statements about the ability of Afirma GSC to improve upon the original Afirma test; and statements about the accuracy of the Xpression Atlas. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, anticipated events and trends, the economy and other future conditions. Forward-looking statements involve risks and uncertainties, which could cause actual results to differ materially, and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: our ability to achieve Medicare coverage for our tests, the market opportunity for the Envisia classifier, the benefits of our tests, the applicability of clinical results to actual outcomes; the laws and regulations applicable to our business, including potential regulation by the Food and Drug Administration or other regulatory bodies; our ability to sell our Afirma tests and successfully transition to our next-generation Afirma GSC; our ability to successfully achieve and maintain adoption of and reimbursement for our products; the amount by which use of our products are able to reduce invasive procedures and misdiagnosis, and reduce healthcare costs; the occurrence and outcomes of clinical studies; and other risks set forth in our filings with the Securities and Exchange Commission, including the risks set forth in our quarterly report on Form 10-Q for the quarter ended June 30, 2018. These forward-looking statements speak only as of the date hereof and Veracyte specifically disclaims any obligation to update these forward-looking statements or reasons why actual results might differ, whether as a result of new information, future events or otherwise, except as required by law.

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